

AMENDMENTS TO THE CLAIMS

1. **(Currently amended)** An assay device to determine the presence of at least one analyte of interest in a liquid sample, the device comprising a test strip on which is deposited:
a first latex-labeled analyte-specific binding reagent means for generating a first signal, or 'test' signal, which indicates the presence and/or amount of analyte of interest in the sample; and
at least 16.5 micrograms of a second latex-labeled specific binding reagent means for generating a second signal, the generation of which second signal indicates both
 - (a) the test has been successfully conducted, and that
 - (b) sufficient time has elapsed following contact of the assay device with the liquid sample for the test to be read and the first signal to have been properly generated.
2. **(Currently amended)** ~~A device according to~~ The device of claim 1, wherein the analyte is hCG.
3. **(Currently amended)** ~~A device according to~~ The device of claim 1, wherein the device is a lateral flow immunochromatographic assay device.
4. (Cancelled)
5. **(Currently amended)** ~~A device according to~~ The device of claim 1, wherein the second signal is generated about 1 minute after the device is contacted with the sample.
6. **(Currently amended)** ~~A device according to~~ The device of claim 1, wherein the second signal is a visible signal which appears in a portion of the test device covered by a layer of translucent material.

7. **(Currently amended)** ~~A device according to~~ The device of claim 1, wherein the second signal has a signal development time of less than 10 seconds.
8. **(Currently amended)** ~~A device according to~~ The device of claim 7, wherein the second signal has a signal development time of less than 8 seconds.
9. (Cancelled)
10. **(Currently amended)** A method of performing an assay to determine the presence of an analyte of interest in a sample, the method comprising the steps of: contacting an assay device according to claim 1 with the sample; observing the appearance of the second signal; ~~and~~ observing the appearance of the first signal when the second signal has appeared; and concluding that the analyte of interest is present in the sample if the first signal appears when the second signal has appeared.
11. **(Currently amended)** ~~A method according to~~ The method of claim 10, wherein the sample is a sample of body fluid.
12. **(Currently amended)** ~~A method according to~~ The method of claim 11, wherein the sample is urine.
13. **(Currently amended)** ~~A method according to~~ The method of claim 10, wherein the analyte of interest is hCG.
14. **(Currently amended)** ~~A device according to~~ The device of claim 1, wherein the sufficient time is a pre-determined time.

15. (New) The device of claim 1, wherein the second latex-labeled specific binding reagent is deposited on the test strip at a position more than 16.5 mm measured from a position at which the liquid sample is to be applied to the test strip.
16. (New) The device of claim 15, wherein the second latex-labeled specific binding reagent is deposited on the test strip at a position less than or equal to 25 mm measured from a position at which the liquid sample is to be applied to the test strip.
17. (New) The device of claim 1, wherein the second latex-labeled specific binding reagent is deposited on the test strip at a position less than or equal to 25 mm measured from a position at which the liquid sample is to be contacted to the test strip.
18. (New) The device of claim 1, further comprising a laminate placed over the deposit of second latex-labeled specific binding reagent.
19. (New) The device of claim 18, wherein the laminate comprises a translucent laminate.
20. (New) The device of claim 1, wherein the device comprises up to about 22 micrograms of second latex-labeled specific binding reagent.
21. (New) The device of claim 1, wherein the first latex-labeled analyte-specific binding reagent comprises a first antibody specific for the at least one analyte of interest.
22. (New) The device of claim 21, wherein the second latex-labeled specific binding reagent comprises a second antibody specific for a third antibody that is specific for the at least one analyte of interest.

23. (New) The device of claim 1, wherein the test strip has a capillary flow time of about 180 seconds per 4 centimeters.
24. (New) A method of making the device of claim 1, comprising:
depositing the first latex-labeled analyte-specific binding reagent on the test strip;
and
depositing the second latex-labeled specific binding reagent on the test strip from a control latex suspension having a latex concentration in the range of about 1.5% to 2% w/v.